

REMARKS

Upon entry of the amendments herein, claims 1, 2 and 27-39 remain pending in the application. Claim 1 has been amended herein.

Claims 1 and 2 remain objected to. The Examiner has reiterated verbatim from the previous Office Action the limitations that are, in his view, acceptable and then states as the reason for maintaining the objection that "[P]resently, R₆ is not limited to non-heterocyclyl." There is no basis for this assessment. As can clearly be seen in Applicants' June 29, 2005 Amendment and Response (see page 5), the definition of R₆ in claim 1 was amended by the deletion of "heterocyclyl"; in other words, R₆ as presently defined in claim 1 is effectively limited to moieties which are nonheterocyclyl. The objection on this basis must be withdrawn.

It should be noted, though, that claim 1 has been further amended herein by deletion of "heterocyclyl" from the definition of component Z of formula I. This is in keeping with the Examiner's requirement that the scope of the pending claims be limited to ones in which "Z is non-heterocyclyl."

The Examiner has not made the present definition of R₁ in claim 1 a basis for objecting to the claims. Nonetheless, in the interest of complete clarity, Applicants wish to point out the following for the record: In the present Office Action, one

of the requirements stated for allowability is that the compounds be limited to ones in which "R₁ is not heterocyclyl containing." However, this is not strictly correct.

In a June 3, 2005 telephone discussion with the undersigned, the Examiner agreed that "six-membered heterocyclyl containing a single heteroatom, which heteroatom is nitrogen" would be acceptable for inclusion in the definition of R₁, but insisted that all other heterocyclic moieties be removed from the definition of R₁. The undersigned agreed to this compromise. The amendments made to claims 1 and 2 in the June 29, 2005 Amendment and Response (see pages 4 and 6) reflect this oral agreement between the Examiner and the undersigned.

Claims 30 and 32 stand rejected as being indefinite because it is allegedly unclear what is to be included in the term "formulation." As a remedy, the Examiner recommends "that the term 'compound' be inserted in place of derivative."

In the first place, the term "compound" already appears in both of the rejected claims, and there is no mention of a derivative anywhere in these claims. Accordingly, the Examiner's suggestion makes no sense. Furthermore, and in any event, the rejected claims represent standard "pharmaceutical formulation" or "pharmaceutical composition" claims reciting a patentable compound in combination with an acceptable carrier. Such claims are routinely found acceptable in applications

wherein compounds are claimed and said compound claims are found acceptable. Applicants also wish to point out that present claim 30 in fact represents original claim 9 amended as suggested by the Examiner in the January 13, 2005 Office Action. There is no basis for this rejection, and it must be withdrawn.

Claims 27 and 28, added by amendment in Applicants' last response, and claims 30, 32, 35 and 37, by virtue of their dependence from claims 27 and 28, have been rejected under 35 U.S.C. §112, first paragraph as not being enabled. The Examiner's indication during the June 3, 2005 telephone discussion that a telephone call regarding any problems subsequently perceived with these claims would precede the issuing of another action did not come to pass.

In any case, this rejection, too, is without merit. In their previous response, Applicants pointed out support, on page 11, lines 1-7 and in the passage running from page 12, line 8 through page 13, line 11 of the specification, for these added claims. Referring to claims 27 and 28, and in particular lines 5-10 of claim 27, the Examiner asserts that "R₆ as defined in claim 1 from which these claims ultimately depend, does not define R₆ as being optionally substituted." It would appear that the Examiner did not fully consider the support cited by Applicants.

While it may be true that claim 1 does not literally recite that R_6 is optionally substituted, focusing on this situation does not appropriately take into account the teaching of the present application. Page 11, lines 1-7; page 12, lines 6-10; and page 12, lines 14-16 provide further teaching as to what is meant by the " C_1 - C_6 alkyl," "aryl" and "cycloalkyl" groups in the definition of substituent R_6 . In each instance, it is taught that the groups can be, inter alia, "substituted or unsubstituted." Lines 6-11 of page 13 teach what is meant by "substituted" in connection with the C_1 - C_6 alkyl, cycloalkyl and aryl groups, as well as the $H_2N-C(Z)-CONH-C(Z)-$ and the $H_2N-C(Z)-$ groups that make up the remainder of the definition of substituent R_6 currently found in claim 1.

Accordingly, it is clear from the disclosure in the specification that (whether it is expressly stated in the claims or not) R_6 can be substituted or unsubstituted, and claim 1 must be interpreted as encompassing both possibilities. Thus, claims 27 and 28 cannot be viewed as directed to subject matter not encompassed by claim 1. Rather, these claims serve to specifically identify ways in which the groups specified in the definition of R_6 can be substituted, when they are substituted.

The Examiner further asserts that "the further definition of R_6 " found in the last 16 lines of claim 27 (which the Examiner has copied into page 4 of the outstanding Office Action) is not

supported by the specification. For reasons similar to those provided above in response to the first part of the Examiner's rejection, this assessment is also unjustified.

Just as when R_6 is a C_1 - C_6 alkyl, cycloalkyl or aryl group, that group may be substituted by the groups set forth on page 13, lines 8-11 of the specification, it is also true that when those substitution groups themselves are alkyl, cycloalkyl, or aryl, they in turn may be substituted by the same list of substitution groups found on page 13, lines 8-11. The original definitions of alkyl, cycloalkyl and aryl groups as optionally being substituted, and the description of what those substitutions may be, apply to these groups in both instances. Thus, the portion of claim 27 copied by the Examiner into lines 4-11 of page 4 of the Office Action is fully supported by the application.

Similarly, "each Z" in the further definition of R_6 in claim 27 may be, according to the definition found in claim 1, H, C_1 - C_6 alkyl, aryl or cycloalkyl. Again, it is taught in the specification that the latter three groups may be substituted or unsubstituted, and the list of substitutions, set forth in the last 8 lines of claim 27 (and copied by the Examiner into lines 12-19 of page 4 of the Office Action), is disclosed on page 13, lines 6-11 of the specification.

It is also important to note that Examples 1-4, 17 and 18 of the instant specification require that R_6 be substituted and thus provide firm and ample support for what was originally intended as the scope of the claimed genus of compounds.

For all the reasons set forth above in addressing this rejection, it must be held that claim 27 and all claims dependent therefrom contain only subject matter which was "described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

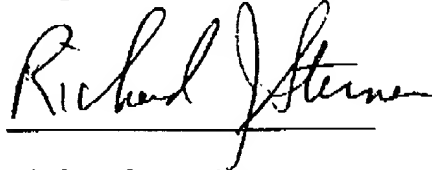
In conclusion, there is no basis for objecting to claims 1 and 2 as being broader in scope than that of the elected subject matter, for rejecting claims 30 and 32 as being indefinite and for rejecting claims 27, 28, 30, 32, 35 and 37 as being nonenabled. Applicants note that the Examiner has indicated claims 29, 31, 33, 34, 36, 38 and 39 will be considered for rejoining to the claims now under consideration, upon a determination of allowable subject matter. Since, as demonstrated beyond a doubt herein, claims 1, 2, 27, 28, 30, 32, 35 and 37 are allowable, it is expected that claims 29, 31, 33, 34, 36, 38 and 39 will now be rejoined and also allowed. Reconsideration and allowance of pending claims 1, 2, and 27-39 are respectfully requested. Again, Applicants request that

should any other matters require attention prior to allowance,
the Examiner contact the undersigned prior to issuance of a
formal action.

The Commissioner is hereby authorized to charge any
additional fees which may be due for any reason in connection
with this communication to Deposit Account No. 23-1703.

Dated: May 2, 2006

Respectfully submitted,

A handwritten signature in black ink, reading "Richard J. Sterner", written over a horizontal line.

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